510(K) SUMMARY

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

FEB 14 2005

Submitter's Name: BIOTEQUE CORPORATION
Address: 8 F-3, No. 136, Sec.3,Jen-Ai Road, Taipei, Taiwan, R.O.C.
Phone: 886-2-2708-3188
Fax: 886-2-2707-6610
Contact: Mr. William Lee (General Manager)

2. Device Name
Trade Name: BIOTEQ® Pigtail Drainage Catheter Set (One Step Type) with Safety String Lock , or without Safety String Lock
Common Name: General Purpose drainage set
Classification name: Catheter, biliary, diagnostic
Catheter, nephrostomy

3. Classification: Class II

4. Predicate Device: URESIL General Purpose Drainage Set (k003753) marketed by URESIL CORP.

5. Device Description: The BIOTEQ® Pigtail Drainage Catheter Set (One Step Type) is used for the drainage pathway of patients' fluids through the catheter out of body . It consist of the following major components:
① F.L.L. Adapter
② Screw Cap
③ Catheter
④ Curve Straightener (Sleeve)
⑤ Wire Cap --- (For With Safety String Lock model only)
⑥ Trocar Stylet
⑦ Trocar Needle
⑧ Sheath
⑨ Suture Wire --- (For With Safety String Lock model only)

6. Intended Use: BIOTEQ® Pigtail Drainage Catheter Set (One Step Type) is intended to be used for percutaneous drainage of abscesses, cysts, gall bladders, nephrostomies and other fluids.

7. Performance Summary: In terms of Physical specification, Chemical specification, Biological specification & Sterilization Specification, the device conforms to applicable standards included ISO 10993 series, ISO 11607-1, ISO 11135, USP Pyrogenic standards & related standards----etc.

8. Conclusions:

The BIOTEQ® Pigtail Drainage Catheter Set (One Step Type) have the same intended use and similar technological characteristics as the URESIL General Purpose Drainage Set (k003753) marketed by URESIL CORP.. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the BIOTEQ® Pigtail Drainage Catheter Set (One Step Type) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2005

Bioteque Corporation
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
3892 South America West Trail
FLAGSTAFF AZ 86001

Re: K033862
Trade/Device Name: BIOTEQ® PIGTAIL Drainage Catheter Set
(One Step Type) with or without Safety String Lock
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Product Code: 78 FGE
Regulation Number: 21 CFR §876.5090
Regulation Name: Suprapubic urological catheter and accessories
Product Code: 78 LJE
Regulatory Class: II
Dated: December 13, 2004
Received: December 17, 2004

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033862

Device Name: BIOTEQ® Pigtail Drainage Catheter Set (One Step Type) with Safety String Lock , or without Safety String Lock

BIOTEQUE CORPORATION

Indications For Use:

BIOTEQ® Pigtail Drainage Catheter Set(One Step Type) is intended to be used for percutaneous drainage of abscesses, cysts, gall bladders and nephrostomies.

Prescription Use V AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033862